

September 29, 2006

The Honorable Henry Waxman United States House of Representatives 2204 Rayburn House Office Building Washington, DC 20515

Dear Congressman Waxman:

The Coalition for a Competitive Pharmaceutical Market (CCPM) strongly commends and applauds you for your leadership and commitment to increasing the timely access to affordable medications for all Americans. The Access to Life-Saving Medicines Act will bring much-needed attention to the glaring need for a viable pathway for approval of safe and effective generic biopharmaceuticals. Creation of such a pathway is critically important to achieving our joint goal of making health care more affordable.

CCPM is an organization of employers, health plans, generic drug manufacturers, pharmacy benefit managers and community pharmacies committed to improving consumer access to safe, affordable pharmaceuticals. CCPM members strongly support public policies that help manage soaring prescription drug costs, which are unsustainable. Continuing to obtain and provide prescription drug coverage is a tremendous challenge, with the skyrocketing costs pressuring reductions in benefits, undermining the ability of CCPM members to compete in the global marketplace and further exacerbating the pressure on Federal health programs.

Availability of safe and effective generic versions of biotech drug products is a top priority for CCPM. Over the past twenty years, there has been a dramatic increase in the number of biopharmaceuticals on the market to treat a wide array of complex diseases. According to industry studies, specialty medications (the vast majority of which are biopharmaceuticals) are the fastest growing segment of drug costs and spending is expected to reach \$40 billion by the end of this year (nearly 20% of the drug spend) and \$100 billion by 2010 (Medco, Drug Trend Report 2005). The development and accessibility of more affordable alternatives for such biotech medicines is absolutely essential to controlling the escalating cost of healthcare, as well as increasing the availability of these lifesaving medicines to more Americans.

It is indisputable that generic versions of biopharmaceuticals would yield significant savings for both private and public sector purchasers while maintaining quality. Indeed, the Coalition believes that the main obstacle standing between consumers and these meaningful savings is lack of an effective abbreviated approval process for such products by the Food and Drug Administration. The Wall Street Journal recognized that the lack of competition among biotech drugs is "...because there is no federal process for gaining approval of generic versions of biotech drugs." (November 15, 2005). Congressional action is urgently needed to achieve this goal and your legislation is an important step towards this end.

We thank you for your leadership and look forward to working with you and other Members of Congress to advance this critical issue.

Sincerely,

Annette Guarisco

Chairman